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DETAILED ACTION

Applicant's amendment in the reply filed on 12/2/09 is acknowledged, with the cancellation of Claims 1-8, 11, and 12; and the additional newly added Claim 13. Claims 9, 10, and 13 are pending. **Claims 9, 10, and 13 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Written Description Rejection

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 10, and 13 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (s) contains subject matter which was not described in the specification in such a way as to reasonable convey to one skilled in the relevant art that the inventor (s), at the time the application was filed, had possession of the claimed invention.

This is a new rejection necessitated by the Applicant's amendment filed on 12/2/09.

The claims are drawn to a "A method of increasing blood count of a subject in a synergistic manner, especially a subject going though a chemotherapy treatment, by orally

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administering the subject with red beet-based composition comprising dry red beet extract; dry *Astragalus membranaceus* extract; and dry *Withania somniferum* extract”.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the claims recite "a method of increasing blood count of a subject in a synergistic manner". However, nowhere in the specification does Applicant mention anything about synergistic promotion that is greater than additive effect. Applicant failed to provide any data in the specification regarding the relative amount of dry red beet extract, dry *Astragalus membranaceus* extract; and dry *Withania somniferum* extract in order to achieve synergistic effect. Does it mean that the combination of any amount of dry red beet extract, dry *Astragalus membranaceus* extract; and dry *Withania somniferum* extract would have synergistic effect that is greater than additive effect? Please note that synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Will the combination of 33.3% dry red beet extract, 33.3% dry *Astragalus membranaceus* extract; and 33.3% dry *Withania somniferum* extract have synergistic effect? Will the combination of 98% dry red beet extract, 1% dry *Astragalus membranaceus* extract; and 1% dry *Withania somniferum* extract have synergistic effect? Will the combination of 1% dry red beet extract, 98% dry *Astragalus membranaceus* extract; and 1% dry *Withania somniferum* extract have synergistic effect? Will the combination of 1% dry red beet extract, 1% dry *Astragalus membranaceus* extract; and 98% dry *Withania*

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somniferum extract have synergistic effect? Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, thus, should be defined in the claim language itself.

Accordingly, in the absence of sufficient recitation of synergistic effect, the specification does not provide adequate written description of the claimed “A method of increasing blood count of a subject in a synergistic manner...”.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed.” (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the relative amounts of dry red beet extract, dry Astragalus membranaceus extract; and dry Withania somniferum extract in order to achieve synergistic effect that is greater than the additive effect. Adequate written description requires more than a mere statement. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

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Further more, Applicant has a misunderstanding about synergistic effect. According to Berenbaum (Berenbaum, Synergy, additivism and antagonism in immunosuppression, Clin Exp Immunol 28: 1-18, 1977), it is clear that synergy is quite complex and very hard to determine and prove. Berenbaum teaches “A combination of agents that is more effective than is expected from the effectiveness of its constituents is said to show synergy” (page 1, last paragraph). Berenbaum further teaches “This approach would be correct only if the effects of drugs were simply proportional to dose, when the effect of a dose of one drug would be the sum of the effects of its constituent quanta. If two or more such drugs given together did not interact pharmacologically, the effect of the combination should similarly be the sum of effects of its constituent quanta. However, because of the nature of drug-receptor interactions, dose-effect curves for biologically active agents are rarely if ever linear. The dose-effect curves have all been found to be markedly non-linear and, considering the complexities of the responses they affect, the likelihood of any not yet investigated being linear appears to be remote, so that this condition is unlikely to be met” (page 2, 2nd paragraph from the bottom). Therefore, “it is wrong to conclude that a drug combination is synergistic merely because the doses chosen produce no effect on their own but are effective when given together, for dose-effect curves may have thresholds” (page 2, 3rd paragraph). Thus, Appellants use fallacious criteria for determining the nature of drug interactions, synergy. The comparison is experimentally straight-forward but, as it is based on assumptions that are wrong, it leads to endless confusion, and conclusions based on it are generally not valid. The correct method for analyzing drug synergism is more laborious and involved, but conclusions based on it may be relied on (page 1, 3rd paragraph). “The proper way to compare different agents having the same effect and non-linear dose-effect curves is to find

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what amount or concentration of each produces the same quantitative effect, i.e., to titrate them. Titration of different agents to the same, easily identifiable end-point is performed as readily with combinations of agents as with single ones and it can therefore be used to compare the effectiveness of combinations of drugs with the effectiveness of their constituents. This approach avoids the pitfall of non-linearity of dose-effect relations and, it enables the formulation of unequivocal definitions of synergy, additiveness and antagonism which can be described in simple mathematical terms” (page 3, 3rd paragraph).

Therefore, the claim (s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor (s), at the time the application was filed, had possession of the claimed invention.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655